required to replace a portion of her injured diaphragm producing a non-functional area of the diaphragm which is contributing to her shortness of breath. These problems are well known complications of open-heart surgery and are directly a result of her IVC filter fragments embolizing to her heart. They are also likely to be long-term problems.

Mrs. Tinlin's post open heart problems will require life-long follow up. It is very likely her tracheomalacia, respiratory compromise/dysfunction, and shortness of breath will progress. She is now at risk for cardiac arrhythmias, cardiac failure and recurrent diaphragm hernias, and she has anxiety about her diaphragm hernia recurring. She will require semi-annual surveillance from a pulmonologist to monitor her shortness of breath from the tracheomalacia and diaphragm injuries. She will require semi-annual cardiology and cardiac surgery follow ups with chest CT scans, echocardiograms, and EKGs to monitor for persistent sternal non-union, arrhythmias, endocarditis, and cardiac dysfunction as a result of the multiple incisions made into her heart during the unconventional open-heart retrieval of her IVC filter fragment. Moreover, Mrs. Tinlin has three more filter struts which have embolized to her lungs. Recent articles in the literature (Kesselman 2018, Trerotola 2017) following pulmonary and cardiac fragments which have embolized suggest early evidence that these fragments may be followed closely clinically with little consequences. Nonetheless, these studies suffer from short follow up and inadequate follow up of their patients. Mrs. Tinlin suffered her first fragment embolization to her heart five years after her Bard Recovery IVC filter was placed. Five years later (10 years after her filter implantation) that fragment perforated her heart causing cardiac tamponade and multi-organ system failure. Clearly reports in the literature with only two years of follow up are inadequate to suggest retain IVC filter fragments can be safely watched. Moreover, pulmonary fragments are known to cause bleeding, hemoptysis, pneumothorax, and death.

Unfortunately, Mrs. Tinlin still has a Recovery IVC filter which has only seven of its twelve struts intact. This imperfect filter needs to be removed and replaced with a more reliable IVC filter. Her current IVC filter has essentially no clot stopping ability as a result of several of its clot catching struts being missing and is unstable. Moreover, an additional strut can embolize at any time to her heart causing her to suffer cardiac tamponade and multi-organ failure again. This filter will require a complex attempt at endovascular removal at a center which specializes in complex filter removals; such as by Dr. Kuo at Stanford Medical Center. If it cannot be removed percutaneously then open removal will be required. A new IVC filter will be required. Had a Simon Nitinol Filter been placed originally these problems would have likely not occurred. Currently a Vena Tech filter should be placed into her IVC as she will require life-long protection form pulmonary embolisms given her difficulty modulating her Coumadin, and her thrombophilia. Mrs. Tinlin has suffered chronic renal failure, exacerbation of her diabetes, and multiple respiratory difficulties as a result of the damage done by the Bard Recovery filter. She has suffered significant chest and back pain from her failed Bard Recovery filter.
At the time Mrs. Tinlin's Bard Recovery filter was implanted, Bard was well aware its retrievable IVC filter had a death rate, fracture rate, migration rate, and perforation rate four to five times its competitors. Yet it continued to sell the defective filter. Bard failed to reveal the contents of their internal studies and analysis of the Bard Recovery filter to implanting physicians and patients. This information was necessary to give informed consent to patients and to understand the performance long term of these filters. This information is something implanting physicians and patients would have wanted to know.